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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,785	04/20/2001	Ted Lau	51831AUSM1	9790

27586 7590 01/31/2005

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,785	LAU ET AL	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29 and 42-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29 and 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/03/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **08/03/04** has been entered.

Applicant adds new claims 42-45, which are related to claims 28-29 and are not new matter.

Accordingly, claims 28-29, 42-45 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Claims 28-29 remain rejected under 35 USC 112, first paragraph, pertaining to lack of enablement for a method of selectively killing prostate cells or a method of treating prostate cancer, for reasons already of record of paper No:15, of 07/12/04.

New claims 42-45 are rejected for the same reasons of record.

Applicant argues that the Examiner clearly is saying that an in vivo example of treating prostate cancer is required in order for the specification to be enabling. Applicant recites *In re Brana*, stating that in vivo data is not necessary to support utility,

and that the concerns raised by the Examiner are ones which would be addressed during the normal preclinical/clinical evaluation of a drug candidate.

Applicant asserts that Prost 03 is a prostate specific target, is a cell surface protein, and that the antibodies specific for Prost 03 stain prostate tumor tissue and prostate metastases.

Applicant recites the reference by Timme et al, 2003, stating that several clinical trials are underway, using radiolabeled antibody to prostate specific membrane antigen, or SGN-15, a doxyrubicin conjugated antibody to Lewis Y antigen that is highly expressed in prostate cancer.

Applicant argues that the Examiner has not shown any information that would make one doubt that PROST03 might be an equally useful therapeutic target, but merely brought up various issues that one would always encounter in the normal process of preclinal drug evaluation.

The recitation of Timme et al is acknowledged.

Applicant arguments have been considered but are found not to be persuasive for the following reasons:

Although in vivo data is not always required, however, in view of the unpredictability of cancer therapy, as overwhelmingly taught by WO93/17715, Gura, Hartwell, and Boon et al, all of record, the lack of adequate disclosure in the specification, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature ot the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In constrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Further, although there were many examples of immunoconjugates comprising antibodies and toxins being used to selectively kill cells, these examples are not applicable to the claimed invention, because different antibodies behave in vivo differently, and one cannot predict that the PROST 03 immunoconjugate used in the claimed method could be used successful in vivo for killing prostate cancer cells or for treating prostate cancer. This issue is clearly shown by White et al, who teach that for a successful immunotherapy, besides the specificity of the antigen, other following properties of the antigen should also be considered: The antigen should be present on all or near all of the malignant cells to allow effective targeting and to prevent a subpopulation of antigen-negative cells from proliferating. Further, antibodies have been developed against a broad spectrum of antigens, and whether the antigens shed, modulate or internalize influence the effectiveness of the administered antibody (p.126,

second paragraph). Moreover, antigen internalization or downregulation can cause repeat dosing to be unsuccessful due to the disappearance of the antibody target (p.126, paragraph before last). Thus, although those skilled in the art at the time the invention was made were aware of these issues, these issues are inherent properties of the antigens, such as antigen shedding, modulating or internalization, and consequently the inherent effectiveness of the immunoconjugate. Applicant however has not shown the properties of the antigens targeted by the antibodies used in the claimed method, such that one could predict the effectiveness of the immunoconjugate of the claimed method in targeting and preventing a subpopulation of antigen-negative cells from proliferating. Applicant has not addressed how to enhance the effectiveness of the immunoconjugate used in the claimed method, if the problem concerning the effectiveness of targeting exists. Thus since the properties or behavior of the antigens and the cancer cells to which the immunoconjugate of the claimed method are not known, it is unpredictable that the immunoconjugate used in the claimed method would effectively target cancer cells in adequate amount for a successful therapy in vivo.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

December 22, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER